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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/058,589 04/10/98 KIMBER

I 138.41.US01

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HM22/0316

EXAMINER

WANG, S

ART UNIT	PAPER NUMBER
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1617

DATE MAILED:

03/16/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary	Application No. 09/058,589	Applicant(s) KIMBER ET AL.	
	Examiner Shengjun Wang	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the corresponding address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- 1) ☒ Responsive to communication(s) filed on 20 December 1999.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) 2-4 and 11-19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 5-7 is/are rejected.
- 7) ☒ Claim(s) 8-10 is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some * c) ☐ None of the CERTIFIED copies of the priority documents have been:
1. ☐ received.
2. ☐ received in Application No. (Series Code / Serial Number) _____.
3. ☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

- | | |
|---|--|
| 14) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 17) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 15) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 18) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 16) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>5&7</u> . | 19) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. Applicant's election with traverse of group I, claims 1, 5-19 in Paper No. 11 submitted on Dec. 20, 1999 is acknowledged. The traversal is on the ground(s) that: a) the inventions are not independent or distinct, and b) no serious burden on the examiner for search. This is not found persuasive because the inventions are distinct as stated in the restriction requirement of Oct. 4, 1999. The claimed method of treating allergen-induced inflammatory disorders, such as skin disorders may be treated with any topical product containing known anti-inflammatory agents. Further, an undue burden of search is seen since the inventions are directed to divergent subject matters, i.e., compositions and method of treatment and the search required for the claimed methods is not required for the claimed compositions. Note here that the search is not limited to the patent files.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 2-4 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Claims 11, and 15-19 are also withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 11.

The claims have been examined herein insofar as they read on the elected invention and species.

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Disclosure Objection

3. The disclosure is objected to because of the following informalities: the apparent typographical error at page 35, line 4 read "Oxaolone/lactoferrin." It should be "Oxaolone/-lactoferrin:".

Appropriate correction is required.

Claim Objections

12-14
4. Claims 8-10 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim can not depend from any other multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claims have not been further treated on the merits.

Claims Rejection 35 U.S.C. – 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Teng et al. in view of Nuijens et al and Enk et al.(Proc. Natl. Acad. Sci. USA, Vol 89, pp 1398-1402, provided in IDS of August, 6, 1998), and Penco et al..

7. Teng et al teach a method of treating dermal inflammatory disorder of human comprising the step of administering a pharmaceutically effective amount of lactoferrin product. See, particularly, page 4, lines 21-30.

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8. Teng et al. do not teach using this method to inhibit the inflammatory activity of IL-1beta in inflammatory dermal disorders.

9. However, Nuijens et al. teach that lactoferrin reduces the production of IL-1beta and TNF alpha and inhibit proliferation. See, particularly, page 287, third paragraph. Enk et al. teach that both IL-1beta and TNFalpha are responsible for promoting inflammatory activity, including the allergen-induced inflammatory activity. See, particularly, the abstract. Penco et al. further teach that lactoferrin inhibits the activity of IL-1beta. See, the abstract.

Therefore it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed invention was made, to use the method of Teng et al. for inhibiting the dermal inflammatory activity of IL-1beta.

A person of ordinary skill in the art would have been motivated to use the method of Teng et al. for inhibiting the dermal inflammatory activity of IL-1beta because lactoferrin is known for reducing the production of IL-1beta and TNFalpha and inhibiting the activity of IL-1beta.

10. Claims 5-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Teng et al. in view of Nuijens et al. and Enk et al. (Proc. Natl. Acad. Sci. USA, Vol 89, pp 1398-1402, provided in IDS of August, 6, 1998).

11. Teng et al teach a method of treating dermal inflammatory disorder of humans comprising the step of administering a pharmaceutically effective amount of lactoferrin product. See, particularly, page 4, lines 21-30.

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12. Teng et al. do not teach specifically to use this method to treat an allergen-induced dermal inflammatory disorder.

13. However, Nuijens et al. teach that lactoferrin reduces the productions of IL-1beta and TNF alpha and inhibit proliferation. See, particularly, page 287, third paragraph. Enk et al. teach that both IL-1beta and TNFalpha are responsible for promoting inflammatory activity, including the allergen-induced inflammatory activity. See, particularly, the abstract.

14. Therefore it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to use the method of Teng et al. for treating an allergen-induced dermal inflammatory disorder.

A person of ordinary skill in the art would have been motivated to use the method of Teng et al. for treating an allergen-induced dermal inflammatory disorder because lactoferrin is known for reducing the production of IL-1beta and TNFalpha and inhibiting the activity of IL-1beta.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang, Ph.D. whose telephone number is (703) 308-4554. The examiner can normally be reached on Monday-Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.


Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

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Shengjun Wang

AU 1617

March 1, 2000


MINNA MOEZIE
PRIMARY EXAMINER